REMARKS

The non-final Office Action dated December 21, 2005, has been carefully considered. Claims 20-37 are pending in the present application, and claims 20, 30, and 34 have been amended to more particularly point out the presently claimed invention. The amendments to claims 20, 30, and 34 are fully supported by the originally-filed specification at, for example, page 4, line 12; page 5, line 17; and page 6, lines 15-35. No new matter has been added by this amendment.

Entry of the above amendments and reconsideration of the present application in view of the following remarks are respectfully requested.

I. CLAIM REJECTION UNDER 35 U.S.C. § 112

Claim 30 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is believed that the amendment to claim 30 has obviated this rejection. In response to the Examiner's query regarding the meaning of alphaolefin, an alphaolefin is an olefin having a double bond at the two end carbons in the carbon chains. Ethylene-alphaolefin copolymers are well known in the art. *See e.g.*, U.S. Patent No. 5,733,980. Thus, claim 30 is believed to be definite.

II. CLAIM REJECTIONS UNDER 35 U.S.C. 103(a)

A. Claims 20-30, 34 and 36 are Patentable over U.S. Patent No. 6,355,058 to Pacetti *et al.* ("Pacetti") in view of U.S. Patent No. 4,749,125 to Escalon *et al.* ("Escallon") and U.S. Patent No. 6,056,993 to Leidner *et al.* ("Leidner")

Claims 20-30, 34 and 36 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pacetti in view of Escallon and further in view of Leidner. This rejection is traversed.

Independent claims 20, 34, and 36 recite methods for coating at least a portion of a medical device including, *inter alia*, providing an implantable medical device (claims 20 and 34) or an implantable stent (claim 36) that has a portion that has a surface adapted for exposure to body tissue of a patient, and applying to the surface a coating formulation comprising a polymeric material and a solvent and a biologically active material (claims 34 and 36) by: (1) providing a nozzle apparatus comprising a chamber connected to at least one opening for dispensing the coating formulation; (2) placing the coating formulation into the chamber; (3) electrically charging the coating formulation; (4) creating droplets of the

electrically charged coating formulation; and (5) depositing the droplets of coating formulation onto the grounded surface to form a coating on the surface. Claims 21-29 depend from claim 20, and thus also include those limitations.

Pacetti does not disclose or suggest the presently claimed method for coating at least a portion of a medical device. As discussed in the Amendment filed on November 5, 2004, Pacetti does not disclose or suggest the use of a nozzle apparatus as required by the present claims. In particular, Pacetti does not disclose or suggest a coating method using a nozzle apparatus in which the coating formulation is first electrically charged before the coating formulation is formed into droplets that are electrically charged. Pacetti does not provide any indication that the electrostatic spraying method that it mentions is a method other than the conventional electrostatic spray coating method. Therefore, the mere disclosure in Pacetti that electrostatic liquid spraying can be used does not teach or suggest the present method, which, unlike conventional electrostatic spraying methods, first electrically charges the coating formulation and then forms droplets from such charged formulation.

Escallon does not remedy the deficiencies of Pacetti. Escallon does not disclose or suggest that its nozzle apparatus may be used in a method for coating at least a portion of an implantable medical device or implantable stent, wherein the portion has a surface adapted for exposure to body tissue of a patient as recited in the present claims. In fact, Escallon does not even disclose or suggest a method for coating an implantable medical device. Accordingly, Escallon does not disclose or suggest providing an implantable medical device such as an implantable stent having a portion that has a surface adapted for exposure to body tissue of a patient as recited in the present claims.

Escallon teaches that its apparatus is used to apply, *inter alia*, pesticides to plants, adhesives to woods, and chemicals to food. (Col. 9, lines 36-41.) Escallon does not disclose or suggest applying to the surface of an implantable medical device a coating formulation comprising a polymeric material and a solvent as presently claimed. With respect to claims 25 and 34-37, Escallon also does not disclose or suggest applying a coating formulation that further includes a biologically active material to the surface of an implantable medical device or implantable stent.

There is no motivation in the disclosures of Pacetti and Escallon to combine the teachings of these references to obtain the present invention. In particular, there is no teaching in Pacetti that an electrostatic spray-coating method in which a coating formulation is first electrically charged and then formed into droplets should be used to coat an implantable medical device. Moreover, Escallon fails to provide any teaching or suggestion that its device should be used to coat implantable medical devices. Thus, neither of these

references provide a motivation to combine its teachings with those of the other. *B.F. Goodrich Company v. Aircraft Braking Systems Corporation*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). Applicant's specification cannot be relied upon to provide such motivation. *See In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Accordingly, Pacetti cannot be combined with Escallon to arrive at the present invention.

Moreover, as acknowledged by the Examiner in the Office Action, Pacetti and Escalon do not disclose the use of the solvents tetrahydrofuran, chloroform, toluene, acetone, isooctane, or tricholoroethane as recited in the present claims.

Leidner does not remedy the deficiencies of Pacetti and Escalon. Leidner is directed to methods of making a prosthesis by spraying fibers onto a rotating mandrel. (Column 1, lines 15-17). As acknowledged by the Examiner, Leidner is directed to making a tubular prosthesis by applying a fiber forming composition on a mandrel, instead of a method of coating a portion of a medical device as presently claimed. Also, Leidner does not disclose or suggest a method of coating a medical device by grounding the surface, providing a nozzle apparatus, placing the coating formulation into the chamber, creating droplets of the electrically charged coating formulation, and depositing the droplets of coating formulation on to the grounded surface to form a coating, as recited in the presently claimed invention. Leidner does not even disclose or suggest depositing electrically charged *droplets* on the surface of a medical device.

Moreover, the combination of Pacetti, Escallon, and Leidner would not result in the presently claimed invention. As discussed above, there is no motivation in Pacetti and Escallon to combine the teachings of these references. The combination of Pacetti and Leidner would not result in the presently claimed invention because both references do not disclose or suggest a method of applying a coating formulation to the surface of an implantable medical device. There is no motivation to combine the teachings of Escallon and Leidner because Escallon does not even disclose or suggest applying a coating formulation to an implantable medical device and Leidner does not disclose or suggest the presently claimed method of applying a coating formulation to an implantable medical device, much less applying a coating composition to the surface of a medical device. Thus, there is no motivation for a person skilled in the art to combine the teachings of Pacetti, Escalon, and Leidner to obtain the presently claimed invention.

Applicant submits that any rejection of the instant claims under Section 103(a) based on these references would indicate the improper use of hindsight gained from Applicant's own specification. As the Federal Circuit has held, hindsight should be avoided in applying the nonobviousness requirement. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1

U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). The Federal Circuit has made very clear that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Thus, claims 20, 34, and 36 and the claims depending therefrom are believed to be patentable over Pacetti in view of Escallon and Leidner. Accordingly, withdrawal of this rejection and allowance of claims 20-30, 34, and 36 are respectfully requested.

B. Claims 20-30, 34 And 36 Are Patentable Over Pacetti In View Of Escalon And U.S. Patent No. 5,695,458 To Shikani *et al.* ("Shikani")

Claims 20-30, 34 and 36 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pacetti in view of Escallon and Shikani. This rejection is traversed.

Claims 20-30, 34, and 36 were shown above to be patentable over Pacetti and Escallon. Shikani does not remedy the deficiencies of Pacetti and Escallon.

Shikani does not disclose or suggest and in fact teaches away from providing an implantable medical device or implantable stent as presently claimed. Instead, Shikani is directed to "anti-infective coatings for *non-implantable* medical devices". (Column 2, lines 16-18). (Emphasis added). Shikani also does not disclose or suggest any method comprising providing an implantable medical device or an implantable stent that has a portion that has a surface adapted for exposure to body tissue of a patient, and applying to the surface a coating formulation comprising a polymeric material and a solvent and a biologically active material (claims 34 and 36) by: (1) providing a nozzle apparatus comprising a chamber connected to at least one opening for dispensing the coating formulation; (2) placing the coating formulation into the chamber; (3) electrically charging the coating formulation; (4) creating droplets of the electrically charged coating formulation; and (5) depositing the droplets of coating formulation onto the grounded surface to form a coating on the surface, as recited in the presently claimed invention.

As discussed above, the combination of Pacetti and Escallon would not result in the present invention because Pacetti and Escallon do not disclose or suggest the solvents as presently claimed. Moreover, there is no motivation to combine the teachings of Pacetti and Escallon where Pacetti does not disclose or suggest a method of applying a coating formulation to a surface of an implantable medical device and Escallon does not even disclose or suggest applying a coating to an implantable medical device. One skilled in the art would also not find motivation to combine the teachings of Pacetti and Shikani where both references do not disclose or suggest the presently claimed method for applying a

coating formulation to an implantable medical device and Shikani teaches away from the use of an implantable medical device. The combination of Escallon and Shikani would not result in the present invention because both references do not disclose or suggest coating an implantable medical device. Thus, one skilled in the art would also find no motivation in the teachings of Pacetti, Escallon, and Shikani to combine the teachings of these references to obtain the presently claimed invention.

Applicant submits that any rejection of the instant claims under Section 103(a) based on these references would indicate the improper use of hindsight gained from Applicant's own specification.

Thus, it is believed that claims 20-30, 34, and 36 are patentable over Pacetti, Escallon, and Shikani. Accordingly, withdrawal of this rejection and allowance of these claims are respectfully requested.

C. Claims 20-30, 32-34, and 36 are Patentable over U.S. Patent Application No. 2002/0081732 to Bowlin *et al.* ("Bowlin")

Claims 20-30, 32-34 and 36 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bowlin. This rejection is traversed.

Bowlin cannot be applied as a reference under 35 U.S.C § 103(a). The present application claims priority to U.S. Patent Application Number 09/954,579, filed September 18, 2001. Bowlin was filed on October 18, 2001, and claims the benefit of provisional application no. 60/241,008 ("the '008 application"), filed October 18, 2000, and provisional application no. 60/270,118 ("the '118 application"), filed February 22, 2001. For Bowlin to apply as prior art, there must be support in the provisional applications. Since the provisional applications do not provide support and Bowlin does not have a filing date before September 18, 2001 (the filing date of the parent application of the present application), Bowlin cannot be considered a prior art reference to the present invention, as discussed below.

The '008 application does not disclose or suggest a method of coating an implantable medical device or implantable stent by grounding the surface, providing a nozzle apparatus, placing the coating formulation comprising a polymer and a solvent and a biologically active material (claims 34 and 36) into the chamber, creating droplets of the electrically charged coating formulation, and depositing the droplets of coating formulation on to the grounded surface to form a coating, as recited in the presently claimed invention. In fact, the '008 application does not even disclose or suggest creating *droplets* of such coating formulation and depositing the droplets on the surface of an implantable medical device to form a coating. Also, as acknowledged by the Examiner, the '008 application does not disclose or suggest the solvents recited in the present claims. In addition, the Examiner refers to U.S. Patent No.

6,592,623 ("the '623 patent"), which is incorporated by reference into the '008 application, for additional support. However, the portions of the '623 patent to which the Examiner cites relate to electrospinning which does not include creating *droplets* of an electrically charged coating formulation and depositing the droplets of coating formulation on the grounded surface to form a coating as recited in the presently claimed invention. *See, e.g.,* '623 patent, column 4, lines 23-27.

The '118 application also does not disclose or suggest a method for coating at least a portion of a medical device including, *inter alia*, providing an implantable medical device or an implantable stent that has a portion that has a surface adapted for exposure to body tissue of a patient, and applying to the surface a coating formulation comprising a polymeric material and a solvent and a biologically active material (claims 34 and 36) by: (1) providing a nozzle apparatus comprising a chamber connected to at least one opening for dispensing the coating formulation; (2) placing the coating formulation into the chamber; (3) electrically charging the coating formulation; (4) creating droplets of the electrically charged coating formulation; and (5) depositing the droplets of coating formulation onto the grounded surface to form a coating on the surface, as recited in the presently claimed invention.

Accordingly, Bowlin, which was filed after the parent application of the present application, cannot be applied as a prior art reference since the '008 and '118 provisional applications do not provide support for the disclosures in Bowlin.

Thus, withdrawal of this rejection and allowance of claims 20-30, 32-34 and 36 are respectfully requested.

III. ALLOWABLE CLAIMS

Claims 31, 35, and 37 have been objected to as being dependent upon rejected base claims (claims 30, 34, and 36, respectively), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. For the reasons discussed above, it is believed that claims 30 and 34, as amended herein, and claim 36 are patentable over the references cited in the Office Action. Thus, it is believed that dependent claims 31, 35, and 37 are also patentable over such references. Accordingly, withdrawal of this objection, and allowance of claims 31, 35, and 37 are respectfully requested.

IV. CONCLUSION

In view of the above remarks and amendments, it is believed that the claim rejections and claim objections have been overcome and that the pending claims are in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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Enclosures